

SEP 16 2002

BLS/JOC/dm 88/041816 9/28/99 Declaration from Dr. Sadler

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CONNELL ET AL.

Application No. 09/087,922

Art Unit: 1723

Filed: April 28, 1998

For: METHOD AND APPARATUS FOR KIDNEY DIALYSIS

Examiner: J. Dredge

Date: September 28, 1999

DECLARATION OF JOHN SADLER, M.D., UNDER 37 C.F.R. § 1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

I, John H. Sadler, M.D., declare as follows:

1. I have read and understand the patent application of Mark E. Connell, et al., Application No. 09/087,922, entitled METHOD AND APPARATUS FOR KIDNEY DIALYSIS.
2. A copy of my *curriculum vitae* is attached hereto as Exhibit A.
3. From about May, 1982, to the present, I have served on the Renal Disease & Detoxification Committee of the Association for Advancement of Medical Instrumentation (AAMI). This committee creates standards for all hemodialysis devices manufactured or distributed in the United States. I have chaired this committee since about November, 1987.
4. I have been affiliated with the Panel on Gastroenterology/Urology-Nephrology Devices of the United States Food and Drug Administration (FDA) since 1988. I chaired this panel from 1987 to 1990, and I have served as a consultant to this committee since 1990. This FDA panel reviews all medical devices used in nephrology and urology, including all hemodialysis machines.

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5. From about July 1994 to the present, I have served as a co-principal investigator in the Patient Outcomes Research Team on Dialysis (CHOICE) Study conducted at Johns Hopkins University. This study, funded by the Agency for Health Care Policy and Research (AHCPR), is a continuing detailed investigation and characterization of kidney dialysis patients, including their treatments and the outcomes of such treatments. The goal of the CHOICE Study was essentially to determine the most effective way to use dialysis as a treatment for kidney disease.

6. During the time period described in paragraphs 3 through 5, I have used, examined, tested, or reviewed more than 12 different hemodialysis machines from at least seven different manufacturers, including the System 1000 Dialysis Delivery System (System 1000) manufactured by Althin Medical, Inc. (Althin).

7. I understand the System 1000 is one embodiment described in the patent application referenced in paragraph 1.

8. From about 1999 to the present, worked as a consultant for Althin. My services have included commenting on developments, offering advice on clinical practice, and attending advisory meetings. While I have received monetary compensation from Althin for these services, I receive no direct financial or other economic benefit from sales of the System 1000.

9. I believe the System 1000 is the most innovative hemodialysis machine developed in the past fifteen years and one of the most innovative pieces of medical instrumentation I have seen in my career.

10. The key feature of the System 1000 is its touch screen. The touch screen replaces a number of necessary electromechanical moving parts and control mechanisms (such as switches, buttons, and dials) of hemodialysis machines. The moving parts of control mechanisms of previous hemodialysis machines were prone to malfunction and needed regular replacement. By replacing most of the moving parts of control mechanisms with a touch screen, the System 1000 eliminated many sources of malfunction inherent in other hemodialysis machines existing at the time the System 1000 made its commercial debut.

11. Additionally, the touch screen of the System 1000 is capable of displaying more information than its contemporary competitor instruments were capable of displaying, and the information displayed on the touch screen of the System 1000 can be changed by changing screens.

12. Moreover, the touch screen of the System 1000 is surprisingly intuitive in its use. Operators of the System 1000 need very little training to be proficient in its use. For example, sixteen System 1000 hemodialysis machines for the IDF Rotunda Center associated with the University of Maryland School of Medicine were ordered in 1992. The machines were due to be delivered in August 1992 but due to shipping difficulties, did not actually arrive until September 1992. Due to these shipping problems, Althin was unable to provide a training nurse to train the Center staff. However, using only a few pages copied from the System 1000 operating manual and some assistance from telephone conversations with an Althin technician, we were able to set up all of the System 1000 machines within a few hours over a weekend and began using them on patients the following Monday (without the assistance of a training nurse). I do not believe we could have accomplished these tasks with any other hemodialysis machine available at the time since operators of other hemodialysis machines (lacking a touch screen) generally require several hours of training, including about one to three days with a training nurse on-site who instructs and helps solve problems.

13. While almost all hemodialysis machines use microprocessors, the System 1000 was the first to employ a complete computer, including a motherboard. Because of this computer, the System 1000 machine is easy to program (using the touch screen) and has proved to be surprisingly stable and reliable. Thus, the touch screen represents an important and substantial technical advancement in hemodialysis machine technology, especially when viewed in light of other hemodialysis machines available at the time the System 1000 made its debut.

14. I believe other unique and innovative features of the System 1000 include: (a) its tall and slender profile, which takes up very little floor space; (b) its smooth control surface, which prevents liquids from seeping into the machine, a common cause of malfunction in other hemodialysis machines; (c) the placement and layout of blood tubing is so obvious that instruction is not necessary—an operator can intuitively know how blood tubing should be placed simply by looking at the machine; (d) the clamp that holds the dialyzer was cleverly designed and remains better than similar clamps on other hemodialysis machines; and (e) the design allows easy maintenance and servicing.

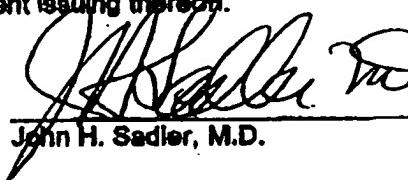
15. While other manufacturers have tried to develop a hemodialysis machine that is simple to use, reliable, and easy to maintain, I believe the System 1000 remains the state of the art in hemodialysis machines today, even though it first appeared almost ten years ago.

16. I know of no other hemodialysis machine that was manufactured with a touch screen prior to the System 1000. While other machines used a screen to display data and error functions, such screens were much different than the touch screen of the System 1000 because they could not be used to control the machine itself.

17. At the time the System 1000 was released, it represented a truly novel and surprisingly innovative development in the market of hemodialysis machines. In this regard, I have noticed that virtually every competitor of Althin has developed, since the System 1000 made its debut, a respective hemodialysis machine that includes many of the innovations that first appeared in the System 1000.

18. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further, these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

Date: 29 Sept, 1999



John H. Sadler, M.D.

CURRICULUM VITAE

John Holland Sadler, M.D.

Associate Professor of Medicine
Division of Nephrology
Department of Medicine
University of Maryland School of Medicine
Baltimore, Maryland 21201

Born: December 10, 1935
Greenville, South Carolina

Citizenship: U.S.A.

Married, 2 adult children

EDUCATION

1960 M.D., B.S. in Medicine, Duke University School of Medicine

Internship
1960-1961 Intern in Medicine
Emory University School of Medicine
Grady Memorial Hospital
Atlanta, Georgia

Residency
1963-1964 Emory University School of Medicine
V.A. Hospital
Atlanta, Georgia

Fellowship
1961-1963 Fellow in Renal Disease
Emory University School of Medicine
Grady Memorial Hospital
Atlanta, Georgia

LICENSURE Maryland, North Carolina, Georgia (inactive)

MILITARY SERVICE

1964-1966 U.S. Air Force: Chief, Internal Medicine Section
U.S. Air Force Hospital
Sheppard Air Force Base, Texas

Mailing address:
Independent Dialysis Foundation
840 Hollins Street
Baltimore, Maryland 21201

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FACULTY POSITIONS

1966-1967	Instructor in Medicine Emory University School of Medicine Clinical Director Atlanta Artificial Kidney Center Atlanta, Georgia
1967-1969	Assistant Professor of Medicine Emory University School of Medicine Director Atlanta Artificial Kidney Center
1969-1971	Associate Professor of Medicine Emory University School of Medicine Director Atlanta Regional Nephrology Center Grady Memorial Hospital Atlanta, Georgia
1971-1972	Associate Professor of Medicine Associate Chief Division of Renal Disease Medical College of Virginia Richmond, Virginia
1972-1992	Associate Professor of Medicine Head, Division of Nephrology University of Maryland School of Medicine Baltimore, Maryland
1992 - 1994	Associate Professor of Medicine Nephrology Division University of Maryland Baltimore, Maryland
1994 -	Clinical Associate Professor of Medicine Nephrology Division University of Maryland Baltimore, Maryland

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PROFESSIONAL MEMBERSHIPS

American Federation for Clinical Research
American Society of Nephrology
International Society of Nephrology
American Society of Artificial Internal Organs
Intl. Society for Artificial Organs
American Society of Transplant Physicians
Association for Advancement of Medical
Instrumentation (Chair, Renal Disease &
Detoxification Committee 1987 -)
Southeastern Dialysis & Transplant Association
(President 1968)
Renal Physicians Association
(President 1973-1975, Board 1973-1981,
Counselor 1981-1988)
Southeastern Organ Procurement Foundation
(President 1974-1975), Chair, Ethics
Committee 1988 -1990), Chair Computer
Application Committee 1976-1988)
Baltimore City Medical Society
Medical & Chirurgical Faculty of Maryland
American Medical Association
American Association for the Advancement of Science
Kidney Foundation of Maryland
(President 1978-1980)
National Kidney Foundation
Maryland High Blood Pressure Coordinating Council
(1978-1982)
American Heart Association, Council on the Kidney
Royal College of Physicians, Edinburgh, Fellow 1996.

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EXTERNAL APPOINTMENTS

- Maryland Commission on Kidney Disease 1981 - 1990
(Chairman 1985-1990)
- Center for Devices & Radiological Health,
Food and Drug Administration
(Panel on Gastroenterology/Urology -
Nephrology Devices, Member 1986,
Chairman 1987-1990, consultant 1990-)
- ESRD Network 31
(Member 1976-1988, President 1978-1980,
Medical Review Board 1981-1988)
- Kidney Disease Coalition, Chair 1981-1982
(national organization to produce study,
meeting, publication on dialyzer reuse.)
- United Network for Organ Sharing
Ethics Committee Member 1978 - 1992, Chair 1993-1995
- Association for Advancement of Medical Instrumentation
Chair, Renal Disease & Detoxification Committee 1982 -
- International Standards Organization
Renal Replacement, Detoxification & Apheresis Group
(Chairman 1982-)
- Mid-Atlantic Renal Coalition (parent of ESRD Network 5)
(Board Member 1987-)
- Combined Health Agencies
(Board Member 1978 - 1994,
Development Committee 1987-1988
Executive Committee 1990 -1994)
- United Way of Central Maryland
(Board Member 1981-1989)
- Judicial Board, University of Maryland at Baltimore
(Member 1983-1988, Chairman 1988- 1994)
- Institute of Medicine, National Academy of Science,
ESRD Program Study Committee 1988-1990
Organizing Committee,
Conference on Monitoring & Managing Quality
in ESRD 1992.
Conference on Health & Functional Status
in ESRD 1994
- Medical Technology & Practice Patterns Institute; Chair, Technical
Advisory Committee 1992 -

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Independent Dialysis Foundation, President and CEO 1979-
Medical Education Institute: Life Options Rehabilitation
Advisory Council; Member 1993 -1998, Chair 1996-1998.
CHOICE Study, Johns Hopkins University (AHCPR funded
5 year ESRD Patient Outcome Research Team)
Co-Investigator 1994-1999.
ESRD Health Status Outcomes Group, Chair 1995-1997.

HONORS, AWARDS

1960	Borden Undergraduate Research Award Duke University
1983	SEOPF Upjohn Award
1987	AOA Medical Honor Society (Faculty)
1987	Senior Class Teaching Award
1988	Honorary Life Member, Renal Physicians Association
1991	FDA Comissioner's Award
1996	Fellow, Royal College of Physicians, Edinburgh

PUBLICATIONS

Wyngaarden JB, Silberman HR, and Sadler JH. Feedback mechanisms influencing purine ribotide synthesis. Annals of N.Y. Academy of Sciences. 1959.

Tuttle EP and Sadler JH. Measurement of renal tissue fluid turnover by thermodilution techniques. Hypertension Vol. XIII, Proceedings of the High Blood Pressure Research Council, American Heart Association, p. 3-16, 1964.

Sadler JH. Treatment of uremia with chronic hemodialysis. Journal of the Medical Association of Georgia, p. 484, Nov. 1966.

Hunt JR, Sadler JH, Shinaberger JH and Galletti PM. Laboratory and Clinical evaluation of a small countercurrent dialyzer, the mini klung. Transactions ASAIO vol. XIV, p. 109, 1968.

Earnest DR, Sadler JH, Ingram RH and Macon EJ. Acid base balance in chronic hemodialysis. Transactions ASAIO vol. XIV, p. 434, 1968.

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Galletti PM, Sadler JH, Barbour B and Orrell LF. The mini klung and the mini kill, laboratory evaluation of two low prime, high transfer rate hemodialyzers. Proc. Euro. Dial. and Trans. Assoc. IV: p. 35., 1968.

Hyde SE, III, Sadler JH. Red blood cell destruction in hemodialysis. Transactions ASAIO Vol. XV, p. 50, 1969.

Sadler JH. Problems of hemodialysis in transplant patients. Transplantation Proceedings Vol. IV, No. 4, p. 571, 1972.

Flotte CT, Ollodart RM, Lubash G, Young J, Gallagher E, and Sadler JH. Prolonged cold ischemic times compatible with functioning cadaveric renal transplants. American Surgeon 39:261, 1973.

Dagher FJ, Gelber RL, Ramos E and Sadler JH. The use of basilic vein and brachial artery as an A-V fistula for long term towards hemodialysis. J. Surg. Research 20: 373-76, 1976.

Spector DLC, Frost L, Zachary JB, Sterioff S, Rolley RT, Williams GM and Sadler JH. Perfusion nephropathy in human transplants. N. Eng. J. Med. 295-1217, November 25, 1976.

Dagher FJ, Gelber RL, Ramos E and Sadler JH. Basilic vein to brachial artery fistula: A new access for chronic hemodialysis. Southern Medical Journal 69: 1438-1440, 1976.

Adir J, Narang PK, Josselson J., and Sadler JH. Pharmacokinetics of bretylium in renal insufficiency. N. Eng. J. Med. 300:1390-1, 1979.

Josselson J, Pula T, and Sadler JH. Acute rhabdomyolysis associated with an echovirus infection. Arch. Int. Med. 140:1671-2, 1980.

Narang PK, Adir J, Josselson J, Yacobi A, and Sadler JH. Pharmacokinetics of bretylium in man after intravenous administration. J. Pharmacokinetics and Biopharmaceutics 8:363-372, 1980.

Carpenter WT, Sadler JH, Light PD, et al. The therapeutic efficacy of hemodialysis in schizophrenia. N. Engl. J. Med. 308:669-675, 1983

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Reed WP, Light PD, Sadler JH. Access for hemodialysis by means of long-term atrial venous catheters. *Kid. Int.* 25:838-840, 1984.

Reed WP, Light PD, Sadler JH. Right atrial catheters as access for hemodialysis. *Artif. Organs* 8(1):456-460, 1984.

Reed WP, Light PD, and Sadler JH. Single-needle hemodialysis by means of implantable central venous catheters. *First International Symposium on Single Needle Dialysis*, Ed. S. Ringoir, R. Vanholder, P. Ivanovick, ISAO Press, Cleveland, 1984.

Shen SY, Weir MR, Kosenko A, Revie Dr, Ordonez JV, Dagher FJ, Chretien PB, and Sadler JH. Re-evaluation of T-cell subset monitoring in cyclosporine-treated renal allograft recipients. *Transplantation* 40:620-623, 1985.

Shen SY, Weir MR, Litkowski LJ, Anthony DL, Welik RA, Kosenko A, Light PD, Dagher FJ, and Sadler JH. Enzyme-linked immunosorbent assay for serum renal tubular antigen in kidney transplant patients. *Transplantation* 40:642-647, 1985.

Josselson J, and Sadler JH. Nephrotic-range proteinuria and hyper-glycemia associated with clonidine therapy. *AM. J. Med.* 80:545-546, 1986.

Weir MR, Hall-Craggs M, Shen SY, Posner JN, Alongi S, Dagher FJ, and Sadler JH. The prognostic value of eosinophils in acute renal allograft rejection. *Transplantation* 41:709-712, 1986.

Josselson J, Kyser BA, Weir MR and Sadler JH. Hepatitis-B surface antigenemia in a chronic hemodialysis program: lack of influence in morbidity and mortality. *Amer. J. Kid. Dis.* 9:456-461, 1987.

Shen SY, Weir MR, Revie D, Dagher FJ, Chretien P, Bentley FR, and Sadler JH. Differentiation of acute infection from acute cyclosporine nephrotoxicity in renal allograft recipients by peripheral blood T-cell subsets. *Transplantation Proceedings* 19:1776-1779, 1987.

Weir MR, Shen SY, Dagher FJ, Bentley FR, Lesko LJ, and Sadler JH. Effects of allostimulation and cyclosporine therapy on cytotoxic antibody production in highly sensitized prospective renal transplant recipients. *Transplantation* 46:731-739, 1988.

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Sadler JH. Quantity and quality of ESRD treatment in the United States of America. *Contr. Nephrol.* 78:, 1990.

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Rettig, Richard A, John H. Sadler, Klemens B. Meyer, John H. Wasson, George R. Parkerson, Beth Krantz, Ron D. Hays, & Donald L. Patrick. Assessing Health and Quality of Life Outcomes in Dialysis: A report on an Institute of Medicine Workshop. *Am. Journal Kidney Diseases* 30: 1, 1997, pp. 140-155.

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Shen SY, Litkowski LJ, Anthony RL, Light PD, Sadler JH and Dagher FJ Measurement of human renal tubular epithelial antigen in serum by monoclonal antibody and enzyme-linked immunosorbent assay. Proceedings of the International Society of Nephrology, 1984.

Shen SY, Revie DR, Ordóñez JV, Welik RA, Litkowski LJ, Dagher FJ, Sadler JH and Chretien P. T-cell subsets and status of hepatitis-B surface antigen and antibody in end stage renal disease patients. Proceedings of the American Society of Nephrology, 1984.

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John H. Sadler, M.D.
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ABSTRACTS (cont'd)

Weir MR, Josselson J, Bartholomew JR, Bolling G, Yen MD, and Sadler JH. bi-weekly vs. thrice-weekly hemodialysis: Five Year analysis of morbidity and mortality. Proceedings of the American Society of Nephrology. December 1984 (Presented). Kid. Int. 27:175, 1985.

Josselson J, Kyser BA, Weir MR and Sadler JH Chronic hepatitis B antigenemia does not increase morbidity or mortality in hemodialysis patients. American Society of Nephrology. December, 1985. Kid. Int. 29:216, 1986.

Josselson J, Weir MR, Hebel R, Yen M and Sadler JH Mortality risk on maintenance hemodialysis: A five year retrospective analysis. American Society of Nephrology, 18th Annual Meeting, New Orleans, La., 79A, 1985.

Kosenko A, Shen SY, Weir MR, Revie DR, Ordonez JV, Dagher FJ, Sadler JH, and Chretien P. Re-evaluation of T-cell subsets monitoring in renal allograft recipients treated with cyclosporine. May, 1985 (Presented). American Society of Transplant Physicians Abstract Book, 4:10, 1985.

Shen S, Welik R, Zemel S, Weir M, and Sadler J Lymphocytic function and status of hepatitis-B antigen and antibody in hemodialysis patients. National Kidney Foundation. December 1985, American Journal of Kidney Disease, VI:A19, 1985.

Shen SY, Weir MR, Revie D, Dagher FJ, Chretien P, Bentley FR and Sadler JH. Differentiation of acute rejection from acute cyclosporine nephrotoxicity in renal allograft recipients by peripheral blood T-cell subset counts. The 11th International congress of the Transplantation Society, Helsinki, 1986.

Shen SY, Weir MR, Litkowski LJ, Anthony RL, Welik RA, Kosenko A, Light PD, Dagher FJ, and Sadler JH Diagnosis of transplant rejection and cyclosporine toxicity by measurement of human renal proximal tubular epithelial antigen in the serum American Society of Transplant Physicians, May, 1985 (Presented). American Society of Transplant Physicians Abstract Book, 4:39, 1985.

Weir M, Zemel S, Shen S, Welik R, Peppler R, McRoy C, Sadler J, and Leavitt R. Acute effects of hemodialysis on lymphocyte subpopulations and mitogenic response to PHA. American Federation of Clinical Research, Eastern Section, December 1985 (Presented), American Journal of Kidney Diseases, VI:A23, 1985.

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John H. Sadler, M.D.
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ABSTRACTS (cont'd)

Welik R, Josselson J, Shen S, Reed WR, and Sadler JH. Safety and efficacy of repeated low dose streptokinase infusions for declotting hemodialysis subclavian catheters, National Kidney Foundation, Inc., 15th Annual Meeting, New Orleans, La., 1985.

Welik R, Urbaitis B, Weir M, Shen S, Zemel S, McRoy C, Peppler R, and Sadler J. Intracellular ATP level in the lymphocytes of dialysis patients as a possible explanation for decreased mitogenic response. American Federation for Clinical Research, September, 1985 (Presented). Clinical Research, 33:763A, 1985.

Welik R, Urbaitis B, Weir M, Shen S, Zemel S, McRoy C, Peppler R, and Sadler J. Lymphocyte ATP and mitogenic response in normal and hemodialysis patients. American Society of Nephrology, December, 1985. Kid. Int. 29:327, 1986.

Zemel S, Weir M, Welik R, Shen S, Peppler R, McRoy C, and Sadler JH. Effects of age and uremia on lymphocyte mitogenic response in end-stage renal disease patients. American Federation of Clinical Research, Eastern Section, September 1985 (Presented). Clinical Research 33:770A, 1985.

Bentley F, Shen SY, Weir MR, Revie D, Dagher F, Chretien P, and Sadler J. Differentiation of acute rejection from acute cyclosporine nephrotoxicity in renal allograft recipients by peripheral blood T-cell subset counts. International Congress of the Transplant Society, August 1986 (Presented), p. 32.28, 1986.

Josselson J, Weir MR, Hebel JR, Gardner J, Evans D, Sadler JH. Intravenous drug abuse: A marker for shortened survival in patients with end stage renal disease on hemodialysis. American Society of Nephrology, 1986. Kid. Int. 32:234, 1987.

Shen SY, Josselson J, McRoy C, Sadler JH, and Chretien P. Effect of thymosin alpha-1 on heptavax-B vaccination among hemodialysis patients. American Society of Nephrology, 19th Annual Meeting, Washington, D.C., 60A, 1986.

Weir MR, Shen SY, Dagher FJ, Bentley FR, and Sadler JH. A short term analysis of the effect of cyclosporine and source leukocyte transfusions on the cytotoxic antibody production of highly sensitized prospective renal transplant recipients. XI International Congress of the Transplantation Society, August 1986 (Presented). XI Abstract Book, p. 11.1, 1986.

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John H. Sadler, M.D.
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ABSTRACTS (cont'd.)

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Weir MR, Shen SY, Dagher FJ, Bentley FR, and Sadler J. Evaluation of the effects of cyclosporine and source leukocyte transfusions on the immune systems of highly sensitized prospective renal allograft recipients. American Society of Transplant Physicians, 5th Annual Meeting and Scientific Session, 1986.

Shen SY, Zemel S, Weir MR, Dagher FJ, Bentley FR, and Sadler JH. Renal allograft biopsy and conversion from cyclosporine to azathioprine. American Society of Transplant Physicians, 5th Annual Meeting and Scientific Session, Abstract 5:27, 1986.

Shen SY, Josselson J, McRoy C, Sadler JH, and Chretien PB. Effect of thymosin alpha-1 on responses to heptavax-B among hemodialysis patients. Proceedings of the American Society of Nephrology, 1986.

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